



MAY 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Elizabeth Paul  
Manager, Regulatory Affairs  
ConMed Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908

Re: K050519  
Trade/Device Name: Advantage Turbo® Drive System  
Regulation Number: 21 CFR 882.4360  
Regulation Name: Electric cranial drill motor  
Regulatory Class: II  
Product Code: GEY  
Dated: March 15, 2005  
Received: May 2, 2005

Dear Ms. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Elizabeth Paul

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Miriam C. Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K050519  
**Indications for Use**

510(k) Number (if known): K050519

Device Name: Advantage Turbo® Drive System

**Indications for Use:**

The Advantage® Turbo Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Signatory  
Restorative  
Neurological Devices  
K050519

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**PROPRIETARY INFORMATION – LINVATEC CORPORATION**

February 18, 2005

**SUMMARY OF SAFETY AND EFFECTIVENESS**

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the Special 510(k) Summary of Safety and Effectiveness for the Advantage® Turbo Drive System.

**A. Submitter**

Linvatec Corporation  
11311 Concept Boulevard  
Largo, Florida 33773-4908  
Registration Number: 1017294

**B. Company Contact**

Elizabeth Paul  
Manager, Regulatory Affairs  
(727) 399-5234 Telephone  
(727) 399-5264 FAX

*Revised*

**C. Device Name**

Trade Name: Advantage® Turbo Drive System

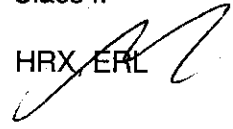
Common Name: Drive System

Classification Names:

1. Ear, Nose and Throat Electrical or Pneumatic Surgical Drill 874.4250
2. Electric Cranial Drill Motor 882.4250
3. Bone Cutting Instrument and Accessories 872.4120
4. Surgical Instrument Motors and Accessories

Proposed Class/Device: Class II

Product Codes: HRX, ERL



**PROPRIETARY INFORMATION – LINVATEC CORPORATION**

Advantage® Turbo Drive System  
Special 510(k) # K050519  
February 18, 2005

**D. Predicate/Legally Marketed Devices**

Advantage Drive System K002523  
Linvatec Corporation

**E. Device Description**

The Advantage® Turbo Drive System device description is identical to the original submission except for the modifications listed below.

The modifications described in this Special 510(K) are listed below:

1. A new motor has been installed which provides additional torque and speed to the handpiece.
2. The software, Version 7.0, has been modified to allow Advantage® Turbo Drive System to run at a maximum forward/reverse speed of 10,000 RMP or 12,000 RPM. This maximum speed is selectable using an appropriate code during the calibration request. All other software parameters used to run the Advantage® Turbo Drive System operate in the same manner as all pre-existing software versions.

These modifications do not affect the device's intended use, fundamental scientific technology or performance specifications so that any new issues regarding safety and effectiveness are raised.

**Intended Use**

The Advantage® Turbo Drive System functions as a powered instrument system consisting of handpieces and accessories to perform cutting of soft tissue and bone. The fields of application include Arthroscopic, Foot, Hand, Medial Sternotomy, Neurosurgical, Orthopedic, Otolaryngological, Oral/Maxillofacial, Plastic/Reconstructive and Spinal surgical procedures.

**F. Substantial Equivalence**

The Advantage® Turbo Drive System is substantially equivalent in intended use, scientific technology and design to the Advantage Drive System. The Advantage Drive System was cleared by FDA under 510(k) K002523. The changes made to the Advantage Drive System have been tested to assure that the proposed modifications do not raise any new issues regarding safety and effectiveness.